Concept Mapping to Develop a Framework for Characterizing Electronic Data Capture (EDC) Systems

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Abstract

CTSAs have brought about a push to find better EDC systems, which facilitate translational research. Based on the data management needs of a specific clinical/translational research lab, concept mapping was used to create a framework to evaluate EDCs. After refinement based on a spiral model, including consultations with the UW CTSA and a survey of other CTSAs, the tool was used to characterize EDCs used at CTSA sites across the country.

Introduction

In spite of the large number of available database tools the majority of clinical investigators continue to use spreadsheets for EDC. In order to help them move to more robust EDC systems we used concept mapping to develop a framework for evaluation of existing EDC systems, then did a preliminary evaluation of the usefulness of this framework by using it on 6 systems, including spreadsheets.

Methods

An open-ended free text survey was given to members of a clinical/translational research lab to assess their expectations and needs for their next generation EDC. The results of this survey were used to create a concept map. The major themes from the concept map were then used to create an evaluation tool.

The resulting tool was refined using a spiral model based on the needs of consultations with researchers for the Institute of Translational Health Sciences (ITHS) (the local CTSA). Any system specifications requested by at least two investigators was added to the tool. The tool was then given to the assistant directors of the CTSA Informatics Cores at Duke University, Oregon Health Sciences University, and the University of Pittsburgh. They in turn suggested additional evaluation criteria that were commonly requested by their users. Based on similarities from these lists the framework was revised.

Tools characterized using the framework were found using inventories created by the National CTSA Inventory Working Group and ITHS. Every effort was made to find online demonstrations. If they were not available, Informatics Core directors were contacted and asked to provide access.

Non-proprietary systems evaluated include, OpenClinica, RedCap (Vanderbilt University), Webtrial (University of Washington), and DADOS (Duke University) as well as generic spreadsheets. The commercial system evaluated is named Velos. Access was initiated by Duke University and followed by a demonstration from the management team at Velos Inc.

Results

The evaluation tool consisted of 24 criteria. Categories of criteria were: data import and export, auto generation of study id, query features, data entry and error checking and auditing, custom forms/ data entry screens, interfaces for reporting including serious adverse event reporting (clinicaltrials.gov and food and drug administration), interface to local systems (electronic institutional review board, electronic master patient index, scheduling), and scheduling and billing support. None of the systems we evaluated provided all functionality.

Of the 6 systems evaluated, 100% were able to import and export data in various formats. Patient tracking and the ability to input information from other locations was available in 85% of systems. However, billing, Internal Review Board (IRB) functionality and institutional level interfaces were only available in 66.7% of systems. Spreadsheets are most often the system. They did not allow for varied functionality, beyond input, import, and export.

Discussion

The most widely provided functionality of EDCs based on our survey is the ability to import and export data, patient tracking, and the ability to accept input from other locations. Additionally, billing and IRB functionality should be considered for inclusion.

References

See http://students.washington.edu/aguid/aim2.html for information about the systems reviewed.